REMARKS

This application has been reviewed in view of the Office Action mailed on November 10, 2005. Claims 1-5, 7-8 and 21-23 are pending in the application with Claims 1 and 21-23 being in independent form. By the present Amendment, Claims 1-5 and 7-8 have been amended in part, Claims 21-23 have been added and Claims 6 and 9-20 have been withdrawn. No new matter is believed to be introduced by the amendments.

In the Office Action, it was provided that Claims 6 and 9-20 were withdrawn from further consideration. The present listing of claims reflects this withdrawal.

In the Office Action, the drawings were objected to under 37 C.F.R. §1.83(a) because the action asserted that the drawings did not show every feature of the invention specified in the claims. Applicants have hereby amended Claim 7 to recite that "at least one of the jaw members includes at least one electrode across the width thereof." Applicants believe that the amendment to Claim 7 overcomes this objection because the claimed features are illustrated in Figure 2 of the application.

Claim 8 was objected to because of a lack of antecedent basis. Applicants have hereby corrected the lack of antecedent basis by replacing "the compressible material" with "the elastomeric material." Accordingly, Applicants respectfully request the withdrawal of this objection.

Claims 1-3 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,086,586 to Hooven. Hooven relates to a bipolar tissue grasping apparatus and tissue welding method.

In the Office Action, it is asserted that Hooven discloses an electrosurgical instrument for sealing tissue, comprising a housing having a shaft attached thereto and an end effector assembly attached to a distal end of the shaft, the end effector assembly including first and second jaw members attached thereto, the jaw members being movable relative to one another from a first position for approximating tissue to at least one additional position for grasping tissue therebetween.

Applicants' invention as claimed relates to a tissue sealing instrument which includes rigid (e.g., stainless steel or polytetraflouroethylene (Teflon)) jaw members which have an elastomeric material or shell disposed thereon. The elastomeric shell includes one or more electrodes disposed therein which are spaced apart a distance X to create a more uniform temperature distribution between the electrodes. Hooven does not disclose or anticipate this arrangement but, rather, it discloses a jaw member made from a polytetraflouroethylene (Teflon) material with electrodes disposed thereon. It can readily be appreciated that not only are Applicants' jaw members different in arrangement, but Applicants' process of manufacturing the jaw members is clearly different and more complex.

Moreover, Applicants define an elastomeric material which is made from a compressible, electrically non-conductive material and is defined as a macromolecular material that returns rapidly to approximately the initial dimension and shape after substantial deformation by a weak stress and release of stress. Hooven's use of Teflon does not meet this definition of an elastomeric material.

Claims 1 and new Claims 21-23, in particular, include a specific compression range of about 0.001 inches to about 0.015 inches when the force used to close the jaw

members is between about 40 psi to about 230 psi for the elastomeric material. These recitations are supported in the application, specifically in the paragraph that begins on page 18 and ends on page 19. Such a compression range is in no way disclosed, described or even remotely anticipated by Hooven.

It is therefore respectfully submitted that in view of the fact that Hooven does not disclose the jaw arrangement nor does Hooven disclose or anticipate the compression range for the elastomeric shell as presently claimed in Applicants' application, the Examiner's rejection under 35 U.S.C. §102(b) is traversed.

Applicants have also hereby amended Claims 1-5 and 7-8 to include the recitation that the instrument is a tissue or vessel sealing instrument. The claimed disclosure relates to tissue or vessel sealing which is clearly more than simply coagulating tissue and vessels as taught by the Hooven patent. Although the Hooven patent relates to so-called "tissue welding," the Hooven patent makes no reference to controlling the necessary parameters to affect efficient and consistent tissue sealing as taught by the present disclosure, namely, controlling the gap distance and providing adequate tissue pressure control to affect a tissue seal. Controlling these parameters during the sealing process allows the tissue to melt, cross link and reform into a generally homogenous mass with limited demarcation between opposing tissue structures when electrical energy is applied. The resulting tissue seal is radically different in appearance, function and quality than simply coagulated tissue.

More particularly, the process of coagulation heats the tissue between the jaw members to a point where the blood coagulates and creates a blockage or clot (a so called

"proximal thrombus") to limit and/or stop the flow of blood through the vessel lumen. A proximal thrombus is notoriously weak and subject to leakage and/or bursting especially when various blood thinners such as aspirin and heparin are introduced into the blood stream (i.e., coagulation produces a treatment site having a low burst strength compared to other closure mechanisms or techniques such as sutures, staples, clips and/or vessel sealing). Applying additional heat to the tissue does not necessarily mitigate these factors and simply further desiccates tissue to a point when the tissue dries and ruptures.

In contrast, vessel sealing is much more complicated than coagulation and involves the melting and reformation (i.e., cross-linking) of the opposing tissue structures into a generally homogenous and unified mass with limited demarcation between opposing tissue walls. The resulting seal provides a much more effective and consistent tissue closure mechanism wherein the likelihood of the vessel bursting under normal systolic conditions (and even exacerbated systolic conditions coughing, sneezing) is *de minimis* at best.

Lastly, it is respectfully submitted that only recently have these distinctions been recognized and appreciated through Applicants' own research and development. To read these important distinctions into the Hooven patent to frustrate the needs of the Applicants would be solely through hindsight recognition, which is clearly impermissible under USPTO guidelines.

In the Office Action, Claims 4-5 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hooven in view of U.S. Patent No. 5,496,312 to Klicek.

Applicants contend that, for at least the reasons discussed above, this obviousness rejection has been overcome.

In the Office Action, Claim 8 was rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Hooven. Applicants contend that, for at least the reasons discussed above, this rejection has been overcome.

New Claims 21-23 have been added are believed to be supported by the application and patentable over the art of record. Claim 21 includes the limitations of amended Claim 1 and most of the limitations of original Claim 2. In Claim 21, Applicants have removed ABS and polycarbonate from the claimed group of elastomeric materials. Thus, Applicants believe that Claim 21 is patentably distinguishable from the art of record.

Claim 22 includes the limitations of amended Claim 1 and most of the limitations of original Claim 3. Applicants have rewritten original Claim 1 as Claim 22 with limitations to the range of the offset distance X. Hooven discloses a range for the offset distance (W_i) of 1 mm to 6 mm (Column 5 Lines 2-3). Claim 22 recites an offset distance X which is in the range of about 0.005 inches (0.127 mm) to less than 0.04 inches (1 mm). This claimed range no longer overlaps the range disclosed in Hooven and Applicants believe that Claim 22 is thus patently distinguishable from the art of record.

Claim 23 includes the limitations of Claim 1 plus the limitation that the distance X is variable depending on the thickness of the tissue between the jaw members. Amended Figure 2, appended hereto and labeled "Replacement Sheet," illustrates this feature. This limitation is supported in Applicants' specification at least on pages 21 and 22 and it is not disclosed in

Hooven. Thus, Applicants believe that Claim 23 is patentably distinguishable form the art of record.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims presently pending in the application, namely Claims 1-5, 7-8 and 21-23, are believed to be in condition for allowance.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicants' undersigned attorney at the Examiner's convenience.

Respectfully submitted,

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